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SERIAL NUMBER FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 08/252,710 06/02/94 EXAMINER RAILEY, J 18M2/0406 PAPER NUMBER ART UNIT PENNIE & EDMONDS 1155 AVENUE OF THE AMERICAS NEW YORK NY 10036-2711 1804 DATE MAILED: 04/06/95 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS FOR RESTRICTION PURPOSES ONLY
This application has been examined, 

Responsive to communication filed on\_\_\_\_\_ month(s), 30 days from the date of this letter. A shortened statutory period for response to this action is set to expire \_ Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133 Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: Notice of Draftsman's Patent Drawing Review, PTO-948. Notice of References Cited by Examiner, PTO-892. 3. Notice of Art Cited by Applicant, PTO-1449. Notice of Informal Patent Application, PTO-152. 5. Information on How to Effect Drawing Changes, PTO-1474. Part II SUMMARY OF ACTION \_\_\_\_\_ are pending in the application. Of the above, claims \_\_\_\_ 2. Claims 3. Claims \_\_\_ 4. Claims 5. Claims are objected to. . are subject to restriction or election requirement. 7. X This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. 9. The corrected or substitute drawings have been received on \_ . Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948). 10. The proposed additional or substitute sheet(s) of drawings, filed on \_ \_. has (have) been approved by the examiner; disapproved by the examiner (see explanation). 11. The proposed drawing correction, filed \_\_\_ \_\_\_\_\_, has been approved; disapproved (see explanation). 12. Acknowledgement is made of the claim for priority under 35 U.S.C: 119. The certified copy has been received not been received been filed in parent application, serial no. \_\_\_\_ ; filed on \_ 13. Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. 14. Other

**EXAMINER'S ACTION** 

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Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-31, drawn to retroviral vectors, classified in Class 435, subclass 320.1.
- II. Claims 32 and 33, drawn to methods of modifying hematopoietic stem cells and treating hematologic disease, classified in Class 424, subclass 93.21.
- III. Claim 34, drawn to synthetic vascular grafts, classified in Class 424, subclass 93.21.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the retroviral vectors can be used to introduce a gene of interest into cells in culture to express biologically important proteins, and not necessarily in gene therapy procedure of Group II which involve modification of stem cells.

In addition, the inventions of Group I and III are related, but

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are distinct products in the art. The product of Group III is made using the product of Group I. Group I has an alternative use for introducing a gene of interest into cells in culture to express biologically important proteins, and not necessarily for producing the product of Group III. In addition, the product of Group III involves the use of "genetically modified" endothelial cells. These cells may be modified by the introduction of nucleic acid through liposomes and not necessarily by the use of recombinant retroviral vectors of Group I.

Groups II and III are independent and distinct inventions in the art, capable of supporting separate patents. Group II is a drawn to a method of modifying hematopoietic stem cells and using these cells in treatment of hematologic disease. Group III is drawn to a vascular graft comprising modified endothelial cells. The type cells modified and the specific uses of those cells are distinct in the art for Groups II and III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification or subject matter, as well as their considerations in the art being distinct, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be

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complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Art Unit 1804 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number for Art Unit 1804 is (703) 308-4312.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. F. Railey, whose telephone number is (703) 308-0281. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Stone, can be reached at (703) 308-3153. The fax phone number for Art Unit 1804 is (703) 308-4312.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JACQUELINE M. STONE SUPERVISORY PATENT EXAMINER GROUP 1800

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Johnny F. Railey II, Ph.D. March 29, 1995